#### **REMARKS**

### STATUS OF CLAIMS

Non-elected claims 61-68 have been cancelled without prejudice to Applicants' right to pursue the subject matter of the cancelled claims in one or more continuation or divisional applications.

Claims 37-60 and 69-74 are pending. Claims 37, 43, 71 and 72 have been amended. Claim 43 has been amended to correct a typographical error. Claims 71 and 72 have been amended to make it clear that both p35 and p40 are subunits of IL-12, and that nucleic acid encoding GM-CSF may also be included in the claimed recombinant viruses. Support for this amendment can be found at page 7, lines 6-8 of the specification. No new matter has been added by virtue of these claim amendments.

New claims 75-77 have been added. Support for new claim 75 can be found at, *inter alia*, page 26, lines 24-30 of the specification. Support for new claims 76 and 77 can be found at, *inter alia*, page 119, lines 22-36 of the specification.

Applicants acknowledge with thanks the Examiner's rejoining of Groups I and II and the rejoining of Groups III and IV.

# REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 37-60 and 69-74 stand rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner contends at pages 2-3 of the June 20, 2001 Office Action (hereinafter "the Office Action") that the recitation of "capable of being expressed" renders the claims vague and indefinite.

Applicants believe that the amendment to claim 37 obviates this rejection since the recitation of "capable of being" has been deleted from the claim.

Reconsideration and withdrawal of this rejection is respectfully requested. Applicants

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attach an annotated version of the claims indicating the amendments made as Exhibit A.

# REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 37-60 and 69-74 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to practice the invention commensurate in scope with these claims. The Examiner acknowledges at page 3 of the Office Action, that the specification is

...enabling for manipulation of the expression of feline CD86 [sic; CD28?], feline CTLA-4 and their ligands feline CD80 and feline CD86 costimulatory molecules in order to regulate T-cell responses, through augmentation, suppression or redirection, to raise a desired immune response towards a particular feline pathogen or feline disease condition (page 2, lines 30-36), [but] does not reasonably provide enablement for a recombinant virus comprising less than the [sic] all the components listed above.

For the purposes of responding to this rejection, Applicants have assumed that the first occurrence of CD86 in the quotation above was intended to be "CD28". If this understanding is incorrect, the Examiner's clarification is respectfully requested.

Applicants contend that the specification does provide enablement for a recombinant virus comprising less than all the components listed above by the Examiner. The specification provides data obtained through the use of a recombinant virus comprising one foreign DNA from the list of components given above by the Examiner as a vaccine.

For example, the recombinant swinepox virus S-SPV-246 (ATCC Accession No. VR-2603) is cited in the specification on page 7, lines 27-34. The description of the S-SPV-246 viral construct is found in the specification on page 88, line 8 to page 90, line 2 and on page 115, lines 3-34. S-SPV-246 contains one of the four immune-enhancing molecules that are listed above, namely feline CD80. It also contains marker genes and

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the genes for the FeLV gag/protease and envelope. Applicants provide data for use of viral strain S-SPV-246 as a recombinant viral vaccine in cats in the specification at page 115, line 3 to the end of page 117. Cats vaccinated with S-SPV-246 were protected from the onset of persistent viremia in an FeLV challenge study as shown in the specification in Table 1 on page 116 to page 117.

Applicants therefore believe that the specification teaches one of ordinary skill in the art how to make and use, and thus is enabling for a, recombinant virus comprising at least one foreign nucleic acid that would function as a vaccine. In light of these comments, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph of claims 37-60 and 69-74.

#### **CONCLUSION**

In view of the above amendments and discussion, reconsideration and withdrawal of theses ground for rejection, and allowance of pending claims 37-60 and 69-77 are respectfully requested.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, Applicants undersigned attorney invites the Examiner to telephone her at the number provided below.

Respectfully submitted,

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EXHIBIT A

### **EXHIBIT A- Version with Markings to Show Changes Made**

- 37. (Amended) A recombinant virus which comprises at least one foreign nucleic acid inserted within a non-essential region of the viral genome of a virus, wherein [each such] <u>said</u> foreign nucleic acid (a) encodes a protein selected from the groups consisting of a feline CD28 protein or an immunogenic portion thereof; a feline CD80 protein or an immunogenic portion thereof; a feline C[d]<u>D</u>86 protein or an immunogenic portion thereof; or a feline CTLA-4 protein or an immunogenic portion thereof and (b) is [capable of being] expressed when the recombinant virus is introduced into an appropriate host.
- 43. (Amended) The recombinant virus of claim 37 comprising more than one foreign nucleic acid wherein all such [foreing] <u>foreign</u> nucleic acids are not inserted into the same nonessential region.
- 71. (Amended) The recombinant virus of claim 69, further comprising a nucleic acid encoding feline GM-CSF or feline [IL12] IL-12[,] p35 [or] and p40.
- 72. (Amended) The recombinant virus of claim 70, further comprising a nucleic acid encoding feline GM-CSF or feline [IL12] IL-12[,] p35 [or] and p40.